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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,843	10/31/2003	Eric Hammill	279.581US1	9309

21186 7590 05/24/2007
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EXAMINER

SMITH, TERRI L

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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05/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/698,843

Applicant(s)

HAMMILL ET AL.

Examiner

Terri L. Smith

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 14-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 24-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1–10 filed on 26 September 2006 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.
2. Applicant's arguments with respect to claims 11–13 filed on 26 September 2006 have been fully considered but they are not persuasive. Examiner respectfully disagrees with Applicant's argument that "Applicant can not find in Verness, for example, means for detecting wear of the insulating layer, wherein the means for detecting wear is disposed within the insulating layer, as recited in claim 11. Claims 12 and 13 depend from claim 11 and thereby include all of its recitations" and "The Office Action has not presented an explanation or a rationale as to why the disclosure of Verness is equivalent to the corresponding elements disclosed in the specification as required by the MPEP § 2183. Applicant respectfully submits that the cited reference does not appear to disclose an equivalent to the corresponding elements disclosed generally in the specification, for instance, Figures 3-12 and the associated written description" (page 10, lines 3–6 and 11–16). Per Applicant's claims 12 and 13, the means for detecting wear of the insulating layer is just a conductive sleeve disposed within the insulating layer and is adapted for exposure with a surrounding environment. Examiner presented an explanation as to why the disclosure of Verness is equivalent to the corresponding elements disclosed in the specification as required by the MPEP § 2183 on page 4 lines 3–5 and page 5 lines 1–3. Consequently, Examiner maintains the rejection submitted in the Office Action mailed on 26 May 2006 and re-submitted herein below.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the Applicant regards as his invention.

4. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Regarding claim 27, "to a surrounding environment" is inferentially included and vague. It is unclear what the surrounding environment is. Everything is exposed to something that surrounds it. Further, it is suggested to positively recite or functionally recite the surrounding environment. If the Applicant wants to claim the surrounding environment, it is suggested to first positively recite the surrounding environment before it is used. If the surrounding environment is being functionally recited it is suggested to use "for" or "adapted to..."

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 11–13 are rejected under 35 U.S.C. 102(b) as being anticipated by Verness et al., U.S. Patent 6,285,910.

7. Referring to claims 11–12, Verness et al. teach an implantable lead that includes a lead body with a proximal end, a distal end, and an insulating layer (e.g., figure 1 and column 2, lines 49–51). The lead has a conductor disposed within the insulating layer and an electrode coupled

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to the lead body and in electrical communication with the conductor (e.g., figures 6 and 7 and column 5, lines 33–49 and column 6, lines 7–19). The lead further has a conductive sleeve within the insulating layer that surrounds the conductor (e.g., figure 15 and column 7, lines 57–61). While Verness et al. do not state the conductive sleeve has a first value in a first condition, it is known that all materials have a resistance to electricity in any given condition and therefore inherently has a first impedance before it is implanted. Regarding claim 13, the second conductive sleeve is disposed within the insulating layer and surrounds the conductor and conductive sleeve, and further surrounds a second conductor (e.g., figure 15 and column 7, lines 57–67 and column 8, lines 1–4).

8. Claims 1–13 and 24–33 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al., U.S. Patent 5,824,030.

9. Regarding claims 1–4, 9–13, 24–28, 32 and 33 Yang et al. disclose a lead body, an insulating layer, a conductor, a pulse generator, a monitoring unit, an electrode and at least one conductive sleeve adapted for electrical isolation from a surrounding environment (e.g., Figs. 1–8, elements 16 (lead body), 25 and 33, (sheath and expandable member (insulating layer)), 52 (conductor), 17 (electrode), 24 (electrode, as shown in Fig. 8, which Examiner is interpreting as a conductive sleeve surrounding conductor 52 and it is electrically isolated from electrode 17 and a surrounding environment as shown by the lead body 16 and insulating layer 25); column 5, lines 53–57; column 10, line 28 (ICD, which Examiner is interpreting as a monitoring unit); column 14, line 5). While Yang et al. do not state a conductive sleeve has a first value in a first condition, and Applicant has not stated what constitutes a first condition or a second condition, it

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is known that all materials have a resistance to electricity in any given condition and therefore it inherently has a first impedance before it is implanted and a second impedance after implantation.

10. With respect to claims 5, 6, 8 and 29–31, Yang et al. disclose a second conductive sleeve surrounds a conductor and at least one conductive sleeve (e.g., Fig. 8, elements 37 (window, which Examiner is interpreting as a second conductive sleeve surrounding conductor 52 and conductive sleeve 24 and it is electrically isolated from electrode 17; column 6, line 45) and a second conductor (e.g., element 50).

11. Regarding claim 7, Yang et al. discloses a first portion, a second portion, and a third portion (e.g., Figs. 2 and 8, element 16 (lead body, first portion), 25 (sheath, second portion) and 33 (expandable member, third portion).

Double Patenting

12. Claim 24 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

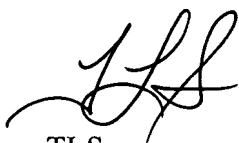
A shortened statutory period for reply to this Final Action is set to expire **THREE MONTHS** from the mailing date of this Action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this Final Action.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

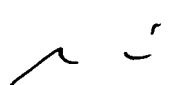
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



TLS
May 17, 2007

17 May 2007



GEORGE R. EVANISKO
PRIMARY EXAMINER

5/17/7